IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SUNDREHAGEN	Docket No.:	7885.81USWO
Serial No.:	10/019866	Filed:	12/21/2001
Int'l Appln No.:	PCT/NO01/00480	Int'l Filing Date:	11/30/2001
Title:	ANALYTIC METHOD AND REAGENT FOR USE THEREOF		

CERTIFICATE UNDER 37 CFR 1.10
'Express Mail' mailing label number: EV037638737US
Date of Deposit: 19 February 2002
I hereby certify that this correspondence is being deposited with the United States Postal Service 'Express Mail Post Office To Addressee' service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C . 20231.

By: _____
Name: Chris Stordahl

PRELIMINARY AMENDMENT

Box PCT
Assistant Commissioner for Patents
Washington, D. C. 20231

Dear Sir:

In connection with the above-identified application filed herewith, please enter the following preliminary amendment.

CLAIMS

Please amend the following claims as indicated below. A marked-up copy of all claims is attached for reference.

5. (amended) A method according to claim 1, characterized by using a reagent comprising fluorescent binding molecules with specific affinity for one analyte, or comprising fluorescent analogues of, or fluorescent fragments of, or fluorescent derivatives of one analyte only.

6. (amended) A method according to claim 1, characterized by the use of a reagent comprising different fluorescent moieties covalently bound to different binding molecules with different specific affinities.

7. (amended) A method according to claim 1, characterized by the use of a reagent comprising one or more peptides or derivatives of peptides with specific binding affinity for an analyte, said binding peptides having a fluorescent residue covalently linked and being constituted by less than 30 amino acids.

10. (amended) A method according to claim 1, characterized by the use of a reagent comprising peptides or derivatives of peptides containing amino acid sequence Ala-Arg-Asn-Arg-Asn or Ala-Arg-Asn-Gly-Asn for quantitation of C-reactive protein.

11. (amended) A method according to claim 1, characterized by the use of a reagent with fluorescent residues with maximum coefficient of absorption at a wavelength above 640 nm.

12. (amended) A method according to claim 1, characterized by the use of a reagent comprising cell lysing substances or anticoagulants or detergents.

13. (amended) A method according to claim 1, characterized by the use of a reagent comprising one or more fluorescent moieties selected from the group consisting of fluoresceine, Texas Red, Cy5, other Cy dye, FluorLink substance, other Cyanin derivatives, Rhodamin, Methyl Rhodamin, Biodypi 630/650-X/MeOH, Biodypi 650/655-X/MeOH, Biodypi FL/MeOH, Biodypi R6G/MeOH, Biodypi TMR-X/MeOH Biodypi TR-X/MeOH or other substance from the Biodipy group of substances, Alexa Fluor Dyes of different wavelengths, Ruthenium ligand complexes, lanthanoid elements such as Europium, Samarium or Terbium complex bound to a chelating ligand like DTPA, EDTA or N1.

14. (amended) A method according to claim 1, characterized by that the polarization of the emitted light is measured as a function of time, either as a continuous kinetic reading or a reading of the change in polarization of the emitted light between two or more time points, or as a measurement of the polarization of the emitted light after a defined point of time.

15. (amended) A method according to claim 1, characterized by that sample material or aliquot of the sample material is constituted by a biological material, or a dilution or an extract or being dissolved from or being filtrated from the said biological material.

16. (amended) A method according to claim 1, characterized by that sample material or aliquot of the sample material is constituted by blood, or blood serum, or blood plasma, or blood cells, or lysate from blood or blood cells, or urine, or cerebrospinal fluid, or tear liquid, or sputum, or semen, or plasma, or semen or material aspirated from the gastro-intestinal tract or feces, or extract or filtrate or suspension of feces, or plant material or extracts thereof, or dissolved plant material or filtrate thereof.

17. (amended) A method according to claim 1, characterized by the use of standards or calibrators comprising known concentrations of the analyte or the analytes, and furthermore wherein the concentration or concentrations of said analyte or analytes in unknown samples is calculated by interpolation of the values obtained from the unknown samples of the standard curve obtained from said known standards or calibrators.

18. (amended) A method according to claim 1, characterized by the use of a standard curve stored in an artificial memory, optionally connected to the fluorescent polarization instrument in use.

19. (amended) A method according to claim 1, characterized by the use of temperature correction algorithms, either generated empirically or theoretically, to compensate for differences

in fluorescence polarization caused by differences in temperature at different time of measurements of standards and unknown samples, or between standards, or between unknown samples.

20. (amended) A method according to claim 1, characterized by being provided in concentrated or dry form, to be diluted or reconstituted before use, the said reagent being provided divided between different compartments for combination into one reagent prior to use.

21. (amended) A reagent for the performance of the method according to claim 1, characterized in that said reagent comprise at least one type of binding molecule with specific affinity for one or more of the said analytes, and said reagent furthermore comprises fluorescent moieties covalently linked to the said binding molecules or fluorescent analogues of or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

23. (amended) A reagent according to claim 21, characterized in comprising binding molecules with specific affinity for one or more of the said analytes and optionally with fluorescent moieties with absorption maximum between 600 nm and 1000 nm, preferably exceeding 620 nm, more preferably exceeding 640 nm, covalently linked to the said binding molecules, and said binding molecules being either of peptide or aptamer composition or being synthetic binders, optionally being identified by combinatory chemistry techniques or phage display or nucleic acid technology.

24. (amended) A reagent according to claim 21, characterized in being as assay reagent comprising peptide binders or binders of derivatives of peptides, including fluorescent derivatives of said binders, containing the amino acid sequence Ala-Arg-Asn-Arg-Asn and/or Ala-Arg-Asn-Gly-Asn.

25. (amended) Use of the method according to claim 1 to determine concentrations of clinically related substances in samples of biological material from living organisms in need thereof.

26. (amended) Kit for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of complex biological fluid, characterized in comprising one or more containers, wherein the container(s) or compartment of the container(s) contains one single reagent, preferably in the fluidal state according to claim 21, and wherein the reagent comprises one or more fluorescence-labelled specific binding molecules towards the analyte(s) to be measured, or a fluorescence-labelled analogue or a fluorescents fragment or a eluorescent derivative of said analyte(s), as well as device for obtaining the exact volume(s) of the complex biological fluid to be tested and that is needed in order to perform the method adequately.

REMARKS

The above preliminary amendment is made to remove multiple dependencies from claims 5, 6,7,10,11-21 and 23-26.

A new abstract page is supplied to conform to that appearing on the publication page of the WIPO application, but the new Abstract is typed on a separate page as required by U.S. practice.

Applicants respectfully request that the preliminary amendment described herein be entered into the record prior to calculation of the filing fee and prior to examination and consideration of the above-identified application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, John J. Gresens (Reg. No. 33,112), at (612) 371.5265.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Dated: 19 February 2002

By _____
John J. Gresens
Reg. No. 33,112

JJG/kjr

7885.81USWO

MARKED-UP COPY OF CLAIMS

5. A method according to [any of the]claim[s] 1[to 4], characterized by using a reagent comprising fluorescent binding molecules with specific affinity for one analyte, or comprising fluorescent analogues of, or fluorescent fragments of, or fluorescent derivatives of one analyte only.

6. A method according to [any of the]claim[s] 1[to 5], characterized by the use of a reagent comprising different fluorescent moieties covalently bound to different binding molecules with different specific affinities.

7. A method according to [any of the]claim[s] 1[to 6], characterized by the use of a reagent comprising one or more peptides or derivatives of peptides with specific binding affinity for an analyte, said binding peptides having a fluorescent residue covalently linked and being constituted by less than 30 amino acids.

10. A method according to [any of the]claim[s] 1[to 9], characterized by the use of a reagent comprising peptides or derivatives of peptides containing amino acid sequence Ala-Arg-Asn-Arg-Asn or Ala-Arg-Asn-Gly-Asn for quantitation of C-reactive protein.

11. A method according to [any of the]claim[s] 1[to 10], characterized by the use of a reagent with fluorescent residues with maximum coefficient of absorption at a wavelength above 640 nm.

12. A method according to [any of the]claim[s] 1[to 11], characterized by the use of a reagent comprising cell lysing substances or anticoagulants or detergents.

13. A method according to [any of the]claim[s] 1[to 12], characterized by the use of a reagent comprising one or more fluorescent moieties selected from the group consisting of

fluoresceine, Texas Red, Cy5, other Cy dye, FluorLink substance, other Cyanin derivatives, Rhodamin, Methyl Rhodamin, Biodypi 630/650-X/MeOH, Biodypi 650/655-X/MeOH, Biodypi FL/MeOH, Biodypi R6G/MeOH, Biodypi TMR-X/MeOH Biodypi TR-X/MeOH or other substance from the Biodipy group of substances, Alexa Fluor Dyes of different wavelengths, Ruthenium ligand complexes, lanthanoid elements such as Europium, Samarium or Terbium complex bound to a chelating ligand like DTPA, EDTA or N1.

14. A method according to [any of the]claim[s] 1[to 13], characterized by that the polarization of the emitted light is measured as a function of time, either as a continuous kinetic reading or a reading of the change in polarization of the emitted light between two or more time points, or as a measurement of the polarization of the emitted light after a defined point of time.

15. A method according to [any of the]claim[s] 1[to 14], characterized by that sample material or aliquot of the sample material is constituted by a biological material, or a dilution or an extract or being dissolved from or being filtrated from the said biological material.

16. A method according to [any of the]claim[s] 1 [to 15], characterized by that sample material or aliquot of the sample material is constituted by blood, or blood serum, or blood plasma, or blood cells, or lysate from blood or blood cells, or urine, or cerebrospinal fluid, or tear liquid, or sputum, or semen, or plasma, or semen or material aspirated from the gastro-intestinal tract or feces, or extract or filtrate or suspension of feces, or plant material or extracts thereof, or dissolved plant material or filtrate thereof.

17. A method according to [any of the]claim[s] 1[to 16], characterized by the use of standards or calibrators comprising known concentrations of the analyte or the analytes, and furthermore wherein the concentration or concentrations of said analyte or analytes in unknown

samples is calculated by interpolation of the values obtained from the unknown samples of the standard curve obtained from said known standards or calibrators.

18. A method according to [any of the]claim[s] 1[to 17], characterized by the use of a standard curve stored in an artificial memory, optionally connected to the fluorescent polarization instrument in use.

19. A method according to [any of the]claim[s] 1[to 18], characterized by the use of temperature correction algorithms, either generated empirically or theoretically, to compensate for differences in fluorescence polarization caused by differences in temperature at different time of measurements of standards and unknown samples, or between standards, or between unknown samples.

20. A method according to [any of the]claim[s] 1[to 19], characterized by being provided in concentrated or dry form, to be diluted or reconstituted before use, the said reagent being provided divided between different compartments for combination into one reagent prior to use.

21. A reagent for the performance of the method according to [any of the]claim[s] 1[to 20], characterized in that said reagent comprise at least one type of binding molecule with specific affinity for one or more of the said analytes, and said reagent furthermore comprises fluorescent moieties covalently linked to the said binding molecules or fluorescent analogues of or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

23. A reagent according to claim[s] 21[to 22], characterized in comprising binding molecules with specific affinity for one or more of the said analytes and optionally with fluorescent moieties with absorption maximum between 600 nm and 1000 nm, preferably exceeding 620 nm, more preferably exceeding 640 nm, covalently linked to the said binding

molecules, and said binding molecules being either of peptide or aptamer composition or being synthetic binders, optionally being identified by combinatory chemistry techniques or phage display or nucleic acid technology.

24. A reagent according to claim[s] 21[to 23], characterized in being as assay reagent comprising peptide binders or binders of derivatives of peptides, including fluorescent derivatives of said binders, containing the amino acid sequence Ala-Arg-Asn-Arg-Asn and/or Ala-Arg-Asn-Gly-Asn.

25. Use of the method according to claim[s] 1[to 20] to determine concentrations of clinically related substances in samples of biological material from living organisms in need thereof.

26. Kit for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of complex biological fluid, characterized in comprising one or more containers, wherein the container(s) or compartment of the container(s) contains one single reagent, preferably in the fluidal state according to [any of the]claim[s] 21[-24], and wherein the reagent comprises one or more fluorescence-labelled specific binding molecules towards the analyte(s) to be measured, or a fluorescence-labelled analogue or a fluorescents fragment or a eluorescent derivative of said analyte(s), as well as device for obtaining the exact volume(s) of the complex biological fluid to be tested and that is needed in order to perform the method adequately.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SUNDREHAGEN	Docket No.:	7885.81USWO
Serial No.:	10/019866	Filed:	12/21/2001
Int'l Appln No.:	PCT/NO01/00480	Int'l Filing Date:	11/30/2001
Title:	ANALYTIC METHOD AND REAGENT FOR USE THEREOF		

CERTIFICATE UNDER 37 CFR 1.10
'Express Mail' mailing label number: EV037638737US
Date of Deposit: 19 February 2002
I hereby certify that this correspondence is being deposited with the United States Postal Service 'Express Mail Post Office To Addressee' service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C . 20231.

By: _____
Name: Chris Stordahl

COMMUNICATION REGARDING PRELIMINARY AMENDMENT

Box PCT
Assistant Commissioner for Patents
Washington, D. C. 20231

Dear Sir:

In connection with the above-identified application, Applicant wishes to bring to the Examiner's attention that the preliminary amendment filed on 21 December 2001 was submitted with improper format. The multiple dependencies were not removed from the amended claims (5-7, 10-21 and 23-26) as listed in the preliminary amendment. The accompanying marked-up copy, however, did remove the multiple dependencies from these claims. The Applicant respectfully requests that the intention to remove all multiple dependencies from this application be viewed on the basis of the marked-up version of said claims and that no multiple dependency fee be charged to the Applicant.

The Applicant encloses herewith a second preliminary amendment in correct format that effectively removes all multiple dependencies. The Applicant requests that this amendment be entered into the record prior to calculation of the filing fee and prior to examination and consideration of the above-referenced application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, John J. Gresens (Reg. No. 33,112), at (612) 371.5265.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
(612)332.5300

Dated: 19 February 2002

By: _____
John J. Gresens
Reg. No. 33,112

JJG/kjr

PRELIMINARY AMENDMENT

Box PCT
Assistant Commissioner for Patents
Washington, D. C. 20231

Dear Sir:

In connection with the above-identified application filed herewith, please enter the following preliminary amendment

IN THE ABSTRACT

Insert the attached Abstract page into the application as the last page thereof.

IN THE SPECIFICATION

A courtesy copy of the present specification is enclosed herewith. However, the World Intellectual Property Office (WIPO) copy should be relied upon if it is already in the U.S. Patent Office.

CLAIMS

5. A method according to any of the claims 1 to 4, characterized by using a reagent comprising fluorescent binding molecules with specific affinity for one analyte, or comprising fluorescent analogues of, or fluorescent fragments of, or fluorescent derivatives of one analyte only.

6. A method according to any of the claims 1 to 5, characterized by the use of a reagent comprising different fluorescent moities covalently bound to different binding molecules with different specific affinities.

7. A method according to any of the claims 1 to 6, characterized by the use of a reagent comprising one or more peptides or derivatives of peptides with specific binding affinity

for an analyte, said binding peptides having a fluorescent residue covalently linked and being constituted by less than 30 amino acids.

10. A method according to any of the claims 1 to 9, characterized by the use of a reagent comprising peptides or derivatives of peptides containing amino acid sequence Ala-Arg-Asn-Arg-Asn or Ala-Arg-Asn-Gly-Asn for quantitation of C-reactive protein.

11. A method according to any of the claims 1 to 10, characterized by the use of a reagent with fluorescent residues with maximum coefficient of absorption at a wavelength above 640 nm.

12. A method according to any of the claims 1 to 11, characterized by the use of a reagent comprising cell lysing substances or anticoagulants or detergents.

13. A method according to any of the claims 1 to 12, characterized by the use of a reagent comprising one or more fluorescent moities selected from the group consisting of fluoresceine, Texas Red, Cy5, other Cy dye, FluorLink substance, other yanin derivatives, Rhodamin, Methyl Rhodamin, Biodypi 630/650-X/MeOH, Biodypi 650/655-X/MeOH, Biodypi FL/MeOH, Biodypi R6G/MeOH, Biodypi TMR-XMeOH Biodypi TR-X/MeOH or other substance from the Biodipy group of substances, Alexa Fluor Dyes of different wavelengths, Ruthenium ligand complexes, lanthanoid elements such as Europium, Samarium or Terbium complex bound to a chelating ligand like DTPA, EDTA or N1.

14. A method according to any of the claims 1 to 13, characterized by that the polarization of the emitted light is measured as a function of time, either as a continuous kinetic reading or a reading of the change in polarization of the emitted light between two

or more time points, or as a measurement of the polarization of the emitted light after a defined point of time.

15. A method according to any of the claims 1 to 14, characterized by that sample material or aliquot of the sample material is constituted by a biological material, or a dilution or an extract or being dissolved from or being filtrated from the said biological material.

16. A method according to any of the claims 1 to 15, characterized by that sample material or aliquot of the sample material is constituted by blood, or blood serum, or blood plasma, or blood cells, or lysate from blood or blood cells, or urine, or cerebrospinal fluid, or tear liquid, or sputum, or semen, or plasma, or semen or material aspirated from the gastro-intestinal tract or feces, or extract or filtrate or suspension of feces, or plant material or extracts thereof, or dissolved plant material or filtrate thereof.

17. A method according to any of the claims 1 to 16, characterized by the use of standards or calibrators comprising known concentrations of the analyte or the analytes, and furthermore wherin the concentration or concentrations of said analyte or analytes in unknown samples is calculated by interpolation of the values obtained from the unknown samples of the standard curve obtained from said known standards or calibrators.

18. A method according to any of the claims 1 to 17, characterized by the use of a standard curve stored in an artificial memory, optionally connected to the fluorescent polarization instrument in use.

19. A method according to any of the claims 1 to 18, characterized by the use of temperature correction algorithms, either generated empirically or theoretically, to

compensate for differences in fluorescence polarization caused by differences in temperature at different time of measurements of standards and unknown samples, or between standards, or between unknown samples.

20. A method according to any of the claims 1 to 19, characterized by being provided in concentrated or dry form, to be diluted or reconstituted before use, the said reagent being provided divided between different compartments for combination into one reagent prior to use.

21. A reagent for the performance of the method according to any of the claims 1 to 20, characterized in that said reagent comprise at least one type of binding molecule with specific affinity for one or more of the said analytes, and said reagent furthermore comprises fluorescent moities covalently linked to the said binding molecules or fluorescent analogues of or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

23. A reagent according to claims 21 to 22, characterized in comprising binding molecules with specific affinity for one or more of the said analytes and optionally with fluorescent moities with absorption maximum between 600 nm and 1000 nm, preferably exceeding 620 nm, more preferably exceeding 640 nm, covalently linked to the said binding molecules, and said binding molecules being either of peptide or aptamer composition or being synthetic binders, optionally being identified by combinatory chemistry techniques or phage display or nucleic acid technology.

24. A reagent according to claims 21 to 23, characterized in being as assay reagent comprising peptide binders or binders of derivatives of peptides, including fluorescent

derivatives of said binders, containing the amino acid sequence Ala-Arg-Asn-Arg-Asn and/or Ala-Arg-Asn-Gly-Asn.

25. Use of the method according to claims 1 to 20 to determine concentrations of clinically related substances in samples of biological material from living organisms in need thereof.

26. Kit for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of complex biological fluid, characterized in comprising one or more containers, wherein the container(s) or compartment of the container9s) contains one single reagent, preferably in the fluidal state according to any of the claims 21-24, and wherein the reagent comprises one or more fluorescence-labelled spesific binding molecules towards the analyte(s) to be measured, or a fluorescence-labelled analogue or a fluorescents fragment or a eluorescent derivative of said analyte(s), as well as device for obtaining the exact volume(s) of the complex biological fluid to be tested and that is needed in order to perform the method adequately.

MARKED-UP CLAIMS

5. A method according to [any of the] claim[s] 1 [to 4], characterized by using a reagent comprising fluorescent binding molecules with specific affinity for one analyte, or comprising fluorescent analogues of, or fluorescent fragments of, or fluorescent derivatives of one analyte only.

6. A method according to [any of the] claim[s] 1 [to 5], characterized by the use of a reagent comprising different fluorescent moities covalently bound to different binding molecules with different specific affinities.

7. A method according to [any of the] claim[s] 1 [to 6], characterized by the use of a reagent comprising one or more peptides or derivatives of peptides with specific binding affinity for an analyte, said binding peptides having a fluorescent residue covalently linked and being constituted by less than 30 amino acids.

10. A method according to [any of the] claim[s] 1 [to 9], characterized by the use of a reagent comprising peptides or derivatives of peptides containing amino acid sequence Ala-Arg-Asn-Arg-Asn or Ala-Arg-Asn-Gly-Asn for quantitation of C-reactive protein.

11. A method according to [any of the] claim[s] 1 [to 10], characterized by the use of a reagent with fluorescent residues with maximum coefficient of absorption at a wavelength above 640 nm.

12. A method according to [any of the] claim[s] 1 [to 11], characterized by the use of a reagent comprising cell lysing substances or anticoagulants or detergents.

13. A method according to [any of the] claim[s] 1 [to 12], characterized by the use of a reagent comprising one or more fluorescent moities selected from the group consisting of fluoresceine, Texas Red, Cy5, other Cy dye, FluorLink substance, other yanin derivatives, Rhodamin, Methyl Rhodamin, Biodypi 630/650-X/MeOH, Biodypi 650/655-X/MeOH, Biodypi FL/MeOH, Biodypi R6G/MeOH, Biodypi TMR-XMeOH Biodypi TR-X/MeOH or other substance from the Biodipy group of substances, Alexa Fluor Dyes of different wavelengths, Ruthenium ligand complexes, lanthanoid elements such as Europium, Samarium or Terbium complex bound to a chelating ligand like DTPA, EDTA or N1.

14. A method according to [any of the] claim[s] 1 [to 13], characterized by that the polarization of the emitted light is measured as a function of time, either as a continuous

kinetic reading or a reading of the change in polarization of the emitted light between two or more time points, or as a measurement of the polarization of the emitted light after a defined point of time.

15. A method according to [any of the] claim[s] 1 [to 14], characterized by that sample material or aliquot of the sample material is constituted by a biological material, or a dilution or an extract or being dissolved from or being filtrated from the said biological material.

16. A method according to [any of the] claim[s] 1 [to 15], characterized by that sample material or aliquot of the sample material is constituted by blood, or blood serum, or blood plasma, or blood cells, or lysate from blood or blood cells, or urine, or cerebrospinal fluid, or tear liquid, or sputum, or semen, or plasma, or semen or material aspirated from the gastro-intestinal tract or feces, or extract or filtrate or suspension of feces, or plant material or extracts thereof, or dissolved plant material or filtrate thereof.

17. A method according to [any of the] claim[s] 1 [to 16], characterized by the use of standards or calibrators comprising known concentrations of the analyte or the analytes, and furthermore wherin the concentration or concentrations of said analyte or analytes in unknown samples is calculated by interpolation of the values obtained from the unknown samples of the standard curve obtained from said known standards or calibrators.

18. A method according to [any of the] claim[s] 1 [to 17], characterized by the use of a standard curve stored in an artificial memory, optionally connected to the fluorescent polarization instrument in use.

19. A method according to [any of the] claim[s] 1 [to 18], characterized by the use of temperature correction algorithms, either generated empirically or theoretically, to compensate for differences in fluorescence polarization caused by differences in temperature at different time of measurements of standards and unknown samples, or between standards, or between unknown samples.

20. A method according to [any of the] claim[s] 1 [to 19], characterized by being provided in concentrated or dry form, to be diluted or reconstituted before use, the said reagent being provided divided between different compartments for combination into one reagent prior to use.

21. A reagent for the performance of the method according to [any of the] claim[s] 1 [to 20], characterized in that said reagent comprise at least one type of binding molecule with specific affinity for one or more of the said analytes, and said reagent furthermore comprises fluorescent moities covalently linked to the said binding molecules or fluorescent analogues of or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

23. A reagent according to claim[s] 21 [to 22], characterized in comprising binding molecules with specific affinity for one or more of the said analytes and optionally with fluorescent moities with absorption maximum between 600 nm and 1000 nm, preferably exceeding 620 nm, more preferably exceeding 640 nm, covalently linked to the said binding molecules, and said binding molecules being either of peptide or aptamer composition or being synthetic binders, optionally being identified by combinatory chemistry techniques or phage display or nucleic acid technology.

24. A reagent according to claim[s] 21 [to 23], characterized in being as assay reagent comprising peptide binders or binders of derivatives of peptides, including fluorescent derivatives of said binders, containing the amino acid sequence Ala-Arg-Asn-Arg-Asn and/or Ala-Arg-Asn-Gly-Asn.

25. Use of the method according to claim[s] 1 [to 20] to determine concentrations of clinically related substances in samples of biological material from living organisms in need thereof.

26. Kit for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of complex biological fluid, characterized in comprising one or more containers, wherein the container(s) or compartment of the container(s) contains one single reagent, preferably in the fluidal state according to [any of the] claim[s] 21[-24], and wherein the reagent comprises one or more fluorescence-labelled spesific binding molecules towards the analyte(s) to be measured, or a fluorescence-labelled analogue or a fluorescents fragment or a eluorescent derivative of said analyte(s), as well as device for obtaining the exact volume(s) of the complex biological fluid to be tested and that is needed in order to perform the method adequately.

REMARKS

The above preliminary amendment is made to remove multiple dependencies from claims 5, 6,7,10,11-21 and 23-26.

A new abstract page is supplied to conform to that appearing on the publication page of the WIPO application, but the new Abstract is typed on a separate page as required by U.S. practice.

Applicants respectfully request that the preliminary amendment described herein be entered into the record prior to calculation of the filing fee and prior to examination and consideration of the above-identified application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, John J. Gresens (Reg. No. 33,112), at (612) 371.5265.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Dated: December 21, 2001

By _____
John J. Gresens
Reg. No. 33,112

JJG/kjr/jlh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SUNDREHAGEN	Docket No.:	7885.81USWO
Serial No.:	10/019866	Filed:	12/21/2001
Int'l Appln No.:	PCT/NO01/00480	Int'l Filing Date:	11/30/2001
Title:	ANALYTIC METHOD AND REAGENT FOR USE THEREOF		

CERTIFICATE UNDER 37 CFR 1.10
'Express Mail' mailing label number: EV036308629US
Date of Deposit: August 7 2002
I hereby certify that this correspondence is being deposited with the United States Postal Service 'Express Mail Post Office To Addressee' service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C . 20231.

By: _____
Name: John Junkers

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D. C. 20231

Dear Sir:

In connection with the above-identified application filed herewith, please enter the following preliminary amendment:

IN THE SPECIFICATION

Please amend the paragraph beginning on line 4, page 3 to read as follows:

The phage display technique was developed further when the gene sequence for parts of the antibody producing cells was incorporated and systematically varied or permuted in the phage display particles, as described in Collins J. and Röttgen P. (1994); "Hypervariable phagemid display gene banks for the selection of strongly binding ligands, including their use for the isolation of serine protease inhibitors"; European patent application 1994 000 108 689 (April 1994) taken further as US 5925559 <<Phagamids and process of preparation>> issued 20 July

1999, and by Collins, J., Röttgen, (1997); <<Cosmix-plexing a method for recombination....>> EP 97 101 539.1 (31.01.1997), filed by Cosmix GmbH PCT/EP98/00533 (02.02.1998) and WO 98 33901 (06.08.1998).

Please amend the paragraph beginning on line 5, page 33 to read as follows:

Suitable cyanine dyes are further described in US5627027: <<Cyanine dyes as labeling reagents for detection of biological and other materials by luminescence methods>> by Waggoner; Alan S, 6 May 1997. Furthermore, suitable substances are described in the prior art, such as e.g. in Waggoner et al US patent 6008373 or Brush and Reimer US patent 5986086 or Krandiker et al. US patent 5852191 or Kusakata et al. US patent 4847385 or Waggoner's US patent 5569587.

IN THE CLAIMS

Please cancel claims 1-27 without prejudice or disclaimer.

Please add new claims 28-55.

28. (New) A method for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of a complex biological fluid,

characterized by

a) mixing the said sample or aliquot of the said sample with one single reagent, such as a solid, a solution or premixed solution, wherein said reagent being provided in one single container or compartment of a container, and no other reagent is added during the performance of said method, and said reagent comprises at least one type of binding molecule with specific affinity for one or more of the said analytes, and said reagent furthermore comprises fluorescent moieties covalently linked to the said binding molecules forming a binding pair, wherein the said binding

[redacted]

pair comprises an aptamer or another synthetic binder complexed to fluorescent moieties or fluorescent analogues, fragments or derivatives of said analyte, or the said binding pair being a peptide or peptidic synthetic binder complexed with fluorescent moieties wherein this mixing provides an analyte-binding molecule-fluorescent moiety complex of changed size, or the said binding pair comprises an antibody or an immunoactive antibody fraction complexed to fluorescent analogues of or fluorescent fragments of, or fluorescent derivatives of said analyte or analytes wherein this mixing provides a competitive reaction with resulting changed fluorescence and;

b) said mixing resulting in a mixture which is being irradiated with polarized light which permits the exitation of said fluorescent molecules, and

c) measuring the polarization of the emitted light, and

d) calculating the concentration or concentrations of said analyte or analytes.

29. (New) A method according to claim 28,

characterized in that the test sample or the aliquot of a test sample is whole blood or anti-coagulated whole blood.

30. (New) A method according to claim 28,

characterized by using a reagent for each analyte comprising immunocomplexes between

a) an antibody or an immunoactive fragment of an antibody with specific affinity for said analyte or analytes, and

b) fluorescent analogues or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

31. (New) A method according to claim 28,

characterized by using a reagent for each analyte comprising complexes between

a) an aptamer or another synthetic binder with a specific affinity for said analyte, and

b) fluorescent analogues or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

32. (New) A method according to claim 28,

characterized by using a reagent comprising binding molecules with specific affinity for one or more of the said analytes and with fluorescent moieties with absorption maximum between 600 nm and 1000 nm, preferably above 620 nm, covalently linked to said binding molecules, and said binding molecules being either a peptide or being synthetic binders, optionally being identified by combinatory chemistry techniques or phage display or nucleic acid selection technology.

33. (New) A method according to claim 32,

characterized by the use of a reagent comprising peptides or derivatives of peptides containing amino acid sequence Ala-Arg-Asn-Arg-Asn or Ala-Arg-Asn-Gly-Asn for quantitation of C-reactive protein.

34. (New) A method according to claim 28,

characterized by using a reagent comprising fluorescent binding molecules with specific affinity for one analyte, or comprising fluorescent analogues of, or fluorescent fragments of, or fluorescent derivatives of one analyte only.

35. (New) A method according to claim 28,

characterized by the use of a reagent comprising different fluorescent moieties covalently bound to different binding molecules with different specific affinities.

36. (New) A method according to claim 28,

characterized by the use of a reagent comprising one or more peptides or derivatives of peptides with specific binding affinity for an analyte, said binding peptides having a fluorescent residue covalently linked and being constituted by less than 30 amino acids.

37. (New) A method according to claim 36,

characterized in that binding peptide is constituted by less than 20 amino acids.

38. (New) A method according to claim 37,

characterized in that binding peptide is constituted by less than 15 amino acids.

39. (New) A method according to claim 28,

characterized by the use of a reagent with fluorescent residues with maximum coefficient of absorption at a wavelength above 640 nm.

40. (New) A method according to claim 28,

characterized by the use of a reagent comprising cell lysing substances or anti-coagulants or detergents.

41. (New) A method according to claim 28,

characterized by the use of a reagent comprising one or more fluorescent moieties selected from the group consisting of fluoresceine, Texas Red, Cy5, other Cy Dye FluorLink substances, other Cyanin derivatives, Rhodamin, Methyl Rhodamin, Biodypi 630/650-X/MeOH, Biodypi 650/655-X/MeOH, Biodypi FL/MeOH, Biodypi R6G/MeOH, Biodypi TMR-X/MeOH, Biodypi TR-X/MeOH or other substances from the Biodypi group of substances, Alexa Fluor Dyes of different wavelengths, Ruthenium ligand complexes, lanthanoid elements such as Europium, Samarium or Terbium complex bound to a chelating ligand like DTPA, EDTA or N1.

42. (New) A method according to claim 28, characterised by that the polarisation of the emitted light is measured as a function of time, either as a continuous kinetic reading or a reading

of the change in the polarisation of the emitted light between two or more time points, or as a measurement of the polarisation of the emitted light after a defined point of time.

43. (New) A method according to claim 28, characterised by that sample material or aliquot of the sample material is constituted by a biological material, or a dilution or an extract or being dissolved from or being filtrated from the said biological material.

44. (New) A method according to claim 28, characterised by that sample material or aliquot of the sample material is constituted by blood, or blood serum, or blood plasma, or blood cells, or lysate from blood or blood cells, or urine, or cerebrospinal fluid, or tear liquid, or sputum, or semen, or plasma, or semen or material aspirated from the gastro-intestinal tract or feces, or extract or filtrate from the suspension of feces, or plant material or extracts thereof, or dissolved plant material or filtrate thereof.

45. (New) A method according to claim 28, characterised by the use of standards or calibrators comprising known concentrations of the analyte or the analytes, and furthermore wherein the concentration or concentrations of said analyte or analytes in unknown samples is calculated by interpolation of the values obtained from the unknown samples on the standard curve obtained from said known standards or calibrators.

46. (New) A method according to claim 28, characterised by the use of a standard curve stored in an artificial memory, optionally connected to the fluorescent polarisation instrument in use.

47. (New) A method according to claim 28, characterised by the use of temperature correction algorithms, either generated empirically or theoretically, to compensate for differences in fluorescence polarisation caused by differences in temperature at different time of

measurements of standards and unknown samples, or between standards, or between unknown samples.

48. (New) A method according to claims 28, characterised by being provided in concentrated or dry form, to be diluted or reconstituted before use, the said reagent being provided divided between different compartments for combination into one reagent prior to use.

49. (New) A method according to claim 28, characterised in that said reagent comprises at least one type of binding molecule with specific affinity for one or more of the said analytes, and said reagent furthermore comprises fluorescent moieties covalently linked to the said binding molecules or fluorescent analogues of or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

50. (New) A reagent according to claim 49, characterised in that the reagent comprises complexes between a) an antibody or an immunoactive fragment of an antibody or an aptamer or a synthetic binder with specific affinity for at least one analyte and b) fluorescent analogues or fluorescent fragments of or fluorescent derivatives of said analyte or analytes.

51. (New) A reagent according to claim 49, characterised in comprising binding molecules with specific affinity for one or more of the said analytes and optionally with fluorescent moieties with absorption maximum between 600 nm and 1000 nm, preferably exceeding 620 nm, more preferably exceeding 640 nm, covalently linked to the said binding molecules, and said binding molecules being either of peptide or aptamer composition or being synthetic binders, optionally being identified by combinatory chemistry techniques or phage display or nucleic acid selection technology.

52. (New) A reagent according to claim 49, characterised in being an assay reagent comprising peptide binders or binders of derivatives of peptides, including fluorescent

derivatives of said binders, containing the amino acid sequence Ala-Arg-Asn-Arg-Asn and/or Ala-Arg-Asn-Gly-Asn.

53. (New) Use of the method according to claim 28 to determine concentrations of clinically related substances in samples of biological material from living organisms in need thereof.

54. (New) Kit for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of complex biological fluid, characterized in comprising one or more containers, wherein the container(s) or compartment of the container(s) contains one single reagent, preferably in the fluidal state and according to claim 48, and wherein the reagent comprises one or more fluorescense-labelled specific binding molecules towards the analyte(s) to be measured, or a fluorescence-labelled analogue or a fluorescent fragment or a fluorescent derivative of said analyte(s), as well as device for obtaining the exact volume(s) of the complex biological fluid to be tested and that is needed in order to perform the method adequately.

55. (New) Kit according to claim 54, characterized in that the reagent which is contained in a container or a compartment of a container, is formed to a ready-for-use reagent by mixing the content from different containers prior to or immediately prior to or in connection with the execution of the analysis.

REMARKS

The above preliminary amendment is made to correct minor typographical errors in the specification and to add new claims 28-55.

Applicants respectfully request that the preliminary amendment described herein be entered into the record prior to calculation of the filing fee and prior to examination and consideration of the above-identified application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, John J. Gresens (Reg. No. 33,112), at (612) 371.5265.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Dated: August 7, 2002

By _____
John J. Gresens
Reg. No. 33,112

JJG/nel

MARKED UP COPY OF THE SPECIFICATION

The phage display technique was developed further when the gene sequence for parts of the antibody producing cells was incorporated and systematically varied or permuted in the phage display particles, as described in Collins J. and Röttgen P. (1994); "Hypervariable phagemid display gene banks for the selection of strongly binding ligands, including their use for the isolation of serine protease inhibitors"; European patent application 1994 000 108 689 (April 1994) taken further as US [592559]5925559 <<Phagamids and process of preparation>> issued 20 July 1999, and by Collins, J., Röttgen, (1997); <<Cosmix-plexing a method for recombination....>> EP 97 101 539.1 [(06.02.1997)](31.01.1997), filed by Cosmix GmbH PCT/EP98/[00533]00533 (02.02.1998) and WO 98 33901 (06.08.1998).

Suitable cyanine dyes are further described in US5627027: <<Cyanine dyes as labeling reagents for detection of biological and other materials by luminescence methods>> by Waggoner; Alan S, 6 May 1997. Furthermore, suitable substances are described in the prior art, such as e.g. in Waggoner et al US patent 6008373 or Brush and Reimer US patent [5988086]5986086 or Krandiker [&]et al. US patent 5852191 or Kusakata [&]et al. US patent 4847385 or Waggoner's US [P]patent 5569587.